REMARKS/ARGUMENTS

Specification

In the specification, the paragraphs [0013] and [0027] have been amended to correct obvious errors due to misprints without adding new matters. The following is a quotation of MPEP 2163.07, II OBVIOUS ERRORS. "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction." *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

In paragraphs [0013] and [0027], the word "isobutyl" should be used for chemical group R1 ($-CH_2-CH(CH_3)_2$), instead of "t-butyl". The sentences in the paragraphs are now read "wherein R1 is isobutyl". No other changes are made in these two paragraphs. Applicants respectfully ask the Examiner to allow these amendments to correct the obvious errors that the applicants made in the specification of their original application.

Claims

The first Office Action mailed on February 25, 2004, has been received and reviewed. Claims 1-18 are pending in the application. Claims 1-18 presently stand rejected. As of this amendment, Applicants have canceled Claims 1-2, 10, and 12 without prejudice or disclaimer. Additionally, Applicants have amended Claims 3-9, 11, and 13, 14,18. As of this amendment, Claims 3-9, 11, and 13, and 14-18 are believed to be in condition for allowance and Applicants respectfully request reconsideration of the application as amended herein.

Rejections under 35 U.S.C § 112, second paragraph

The Examiner has rejected Claims 1-18 under 35 U.S.C § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In 1 Y is not defined. In 3 the formula in parenthesis depicts an isobutyl and not the recited t-butyl group. In 4 'therapeutically' should be inserted before 'effective'. 'Chemically modified compound' is vague and indefinite in 10. Therapeutically effective should be inserted before 'salt' in 11. 'Prodrug' in claim 12 is vague and indefinite."

Applicants have canceled Claims 1-2, 10, and 12 without prejudice or disclaimer as of this Amendment. Applicants also have amended Claims 3-9, 11, 13, 14, and 18 as further detailed below.

Regarding Claim 3, applicants have corrected the misprint "t-butyl" by deleting it, and substituted it with the right word "isobutyl".

Regarding Claim 4, applicants have amended the claim by inserting the word "therapeutically" before "effective" to make definition of the claim clear. Also the applicants have inserted the word "An essentially pure" to the compound in the claim to limit the claim further. The applicants have changed the dependency of claim 4, which is originally depended on claim 1, which is now canceled. Now claim 4 is dependent on claim 3.

Regarding Claim 5, applicants have amended the claim by inserting the words ", wherein the composition is" in front of "in oral form" to define the claim clearly.

Regarding Claim 6, applicants have amended the claim by inserting the words ", wherein the composition is" in front of " in intravenous form" to define the claim clearly.

Regarding Claim 7, applicants have amended the claim by inserting the words ", wherein the composition is" in front of " in subcutaneous form." after the words "claim 4" to define the claim clearly.

Regarding Claim 8, applicants have amended the claim by inserting the words ", wherein the composition is" in front of "in intramuscular form." to define the claim clearly.

Regarding Claim 9, applicants have amended the claim by inserting the words ", wherein the composition is" in front of "in inhalation form." to define the claim clearly.

Regarding Claim 11, applicants have inserted the words "therapeutically effective" in front of the word "salt" to define the claim clearly.

Applicants have also amended claim 11 by replacing the words "The chemically modified compound according to claim 10" with the words "The pharmaceutical composition of claim 4" to define the claim clearly and to accommodate the cancellation of claim 10.

Regarding Claim 13, applicants have inserted the words "essentially pure" in front of the word "compound". Applicants have added the words "and purifying" after the word "extracting" to limit the claim further. Applicants have amended the claim to accommodate the cancellation of claim 1 by replacing the words "a compound as claimed in claim 1" with "an essentially pure compound of Formula II..." and the formula with its description.

Regarding Claim 14, applicants have inserted the word "therapeutically" in front of the word "effective amount", and the words "an essentially pure" in front of the word "compound" to limit the claim further. Applicants have amended the claim to accommodate the cancellation of claim 1 by replacing the words "... with said disease an effective amount of compound as claimed in claim 1" with "... suffering with said disease with a therapeutically effective amount of an essentially pure compound of Formula I..." and the formula with its description.

Regarding Claim 15,16 and 17, applicants believe that they are in good conditions and have not made any changes.

Regarding Claim 18, applicants have inserted the word "therapeutically" in front of the word "effective amount", and the words "an essentially pure" in front of the word "compound" to limit the claim further. The claim language is now read as "... a therapeutically effective amount of an essentially pure compound of Formula I ..." instead of "... an effective amount of a compound as claimed in claim1".

Rejections under 35 U.S.C § 101

The Examiner has rejected Claims 1-3 and 18 under 35 U.S.C § 101 for not representing a new invention. The Examiner has pointed out that the compounds recited in Claims 1-3 is not new in nature while the essentially pure compound is.

Applicants have canceled Claims 1-2 without prejudice or disclaimer.

Applicants also amended Claims 3 and 18 as further detailed below.

Regarding Claim 3, applicants have added the limiting word "An essentially pure" in front of the word "compound" in the claim to make the claim specifically complying with 35 USC 101.

Regarding Claim 18, applicants have added the limiting word "An essentially pure" in front of the word "compound" in the claim to make the claim specifically complying with 35 USC 101. Applicants have replaced "... an effective amount of compound as claimed in claim 1" with "... a therapeutically effective amount of an essentially pure compound of Formula I..." and the formula with its description.

Rejections under 35 U.S.C § 102 (a)

The Examiner has rejected Claims 1-2 under 35 U.S.C § 102(a) as being anticipated by Banerji et al, Phytochemistry, vol., p. 897-901 (April 17, 2002). "It discloses the isolation and structural characterization of a compound from Piper brachystachyum Wall denoted as (4). It falls within the genus of claims 1 and 2."

Applicants have canceled Claims 1-2 without prejudice or disclaimer.

ENTRY OF AMENDMENTS

The amendments to Claims 3-9, 11, and 13, 14, 18 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application.

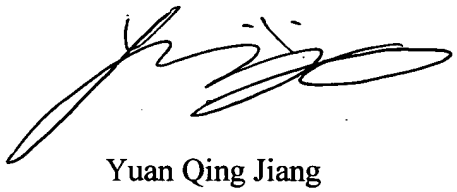
Applicants respectfully request the Examiner to enter the amendments to paragraph [0013] and [0027] in the Specification to correct obvious errors. No new matters are added to the amendments.

CONCLUSION

Claims 3-9, 11, and 13-18 are believed to be in condition for allowance, and an early notice therefore is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned agent.

The commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 502869.

Respectfully Submitted,



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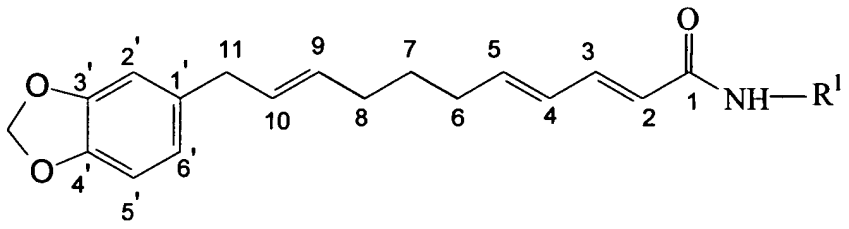
Date: April 2, 2004

Enclosure: Version With Markings to Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

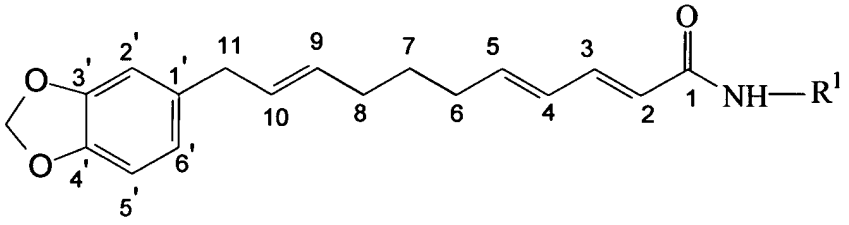
Specification:

[0013]In one embodiment, the invention provides a Laetispicine compound having the following chemical structure of Formula II:



wherein R^1 is [t-butyl group] isobutyl [[](-CH_2-$CH(CH_3)_2$)[]].

[0027] In another embodiment according to the present invention, Laetispicine is isolated and purified from herb Piper laetispicum C. DC. The chemical structure of Laetispicine is shown in Formula II:



wherein R^1 is [t-butyl group] isobutyl [[](-CH_2-$CH(CH_3)_2$)[]].The chemical name of Laetispicine (Formula II) is N-isobutyl-11-(3,4-methylendioxyphenyl)-2E,4E,9E-undecatrienamide. The molecular Formula of Laetispicine is $C_{22}H_{29}NO_3$. Laetispicine is colorless, needle shaped crystals, with the melting point of 93-94 °C. NMR data (Fig. 1) indicate that Laetispicine is a long carbon atom chain with a NH group and some double bonds, attached with a benzene ring with oxygen groups. Animal study showed that the anti-depression effect of Laetispicine is 5

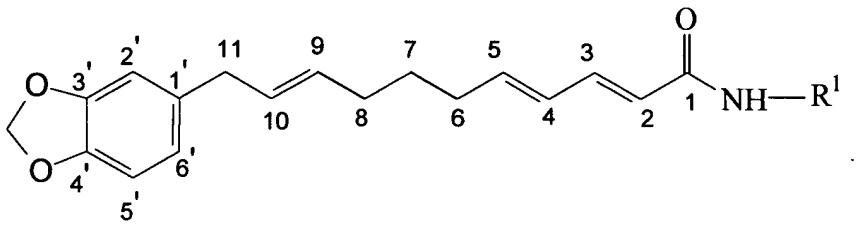
times of that of Fluoxetine (Prozac) (Fig. 2) and the anti-inflammation and pain relieving effect of Laetispicine is equivalent to the effect of Aspirin (Table 2). The details of isolation and purification processes for producing Laetispicine are described in Experiment 1. Methods for obtaining the compounds of Formulas I, II and their analogues are also provided. For example, Formulas II can be extracted from Piper laetispicum C. DC of Piperaceae family, and then it is purified and crystallized. Such extraction techniques include an ethanol extraction followed by an ethyl acetate extraction. Purification of the extracted substance is performed on a silica gel column with standard elution techniques. Formula I and other analogues will be produced by methods of chemical modification of Formula II. Such methods include but not limited to addition, substitution, oxidation, reduction and modification. Other methods of producing the compounds from Piperaceae will be apparent to those of skilled in the art. For example, modifications in column packing, elution buffers, flow rates for eluting the compound may all be modified or changed. Such process modifications are routine to those of skilled in the art.

Claims:

1. (Canceled)

2. (Canceled)

3. (Amended) [A] An essentially pure compound having the following structure of Formula II:



wherein R^1 is [t-butyl group] isobutyl [[] (-CH_2-$CH(CH_3)_2$) []].

4. (Amended) A pharmaceutical composition comprising [an] a therapeutically effective amount of the essentially pure compound as claimed in claim [1] 3 together with at least one pharmaceutically acceptable excipient.

5. (Amended) The pharmaceutical composition of claim 4, wherein the composition is in oral form.

6. (Amended) The pharmaceutical composition of claim 4, wherein the composition is in intravenous form.

7. (Amended) The pharmaceutical composition of claim 4, wherein the composition is in subcutaneous form.

8. (Amended) The pharmaceutical composition of claim 4, wherein the composition is in intramuscular form.

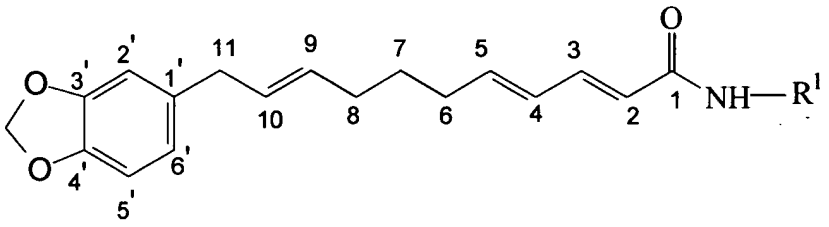
9. (Amended) The pharmaceutical composition of claim 4, wherein the composition is in inhalation form.

10. (Canceled)

11. (Amended) The [chemically modified compound] pharmaceutical composition [according to] of claim [10] 4, wherein said composition is chemically modified as a therapeutically effective [compound is a] salt.

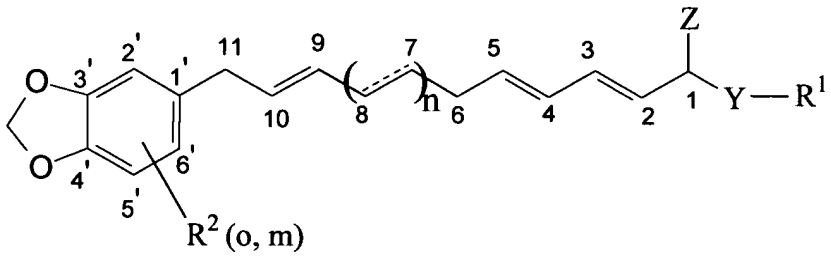
12. (Canceled)

13. (Amended) A method of obtaining [a compound as claimed in claim 1] an essentially pure compound of Formula II:



wherein R^1 is isobutyl ($-CH_2-CH(CH_3)_2$), comprising extracting and purifying the compound from Piper laetispicum of Piperaceae family.

14. (Amended) A method of treating a disease characterized as mental disorder, comprising administering to a patient suffering from said disease with a therapeutically effective amount of an essentially pure compound of Formula I:



wherein R^1 is selected from the group consisting of hydrogen, C_{1-10} alkyl and aromatic cyclic group, R^2 is selected from the group consisting of hydrogen, OR^3, NH_2, NHR^3, and halogen,

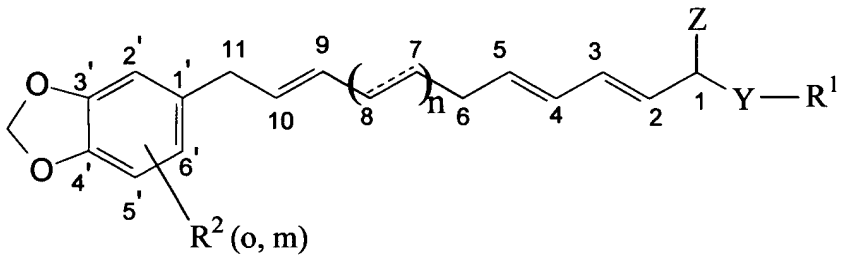
Z is selected from the group consisting of =O, OH, NHR^3 , SH, and SR^3, wherein R^3 is C_{1-10} alkyl or aromatic cyclic group, $(C_7-C_8)_n$ includes at least one single bond or at least one double bond, n is an integer having a value of 0 to 10, and Y is selected from the group consisting of NH, NR^3-, O, and S. [with said disease an effective amount of a compound as claimed in claim 1.]

15. The method of claim 14, wherein the disease is depression.

16. The method of claim 14, wherein the disease is psychopathic disease.

17. The method of claim 14, wherein the disease is Alzheimer's disease.

18. (Amended) A method of alleviating a symptom characterized as inflammation and pain, comprising administering to a subject suffering from said symptom with a therapeutically effective amount of an essentially pure compound of Formula I:



wherein R^1 is selected from the group consisting of hydrogen, C_{1-10} alkyl and aromatic cyclic group, R^2 is selected from the group consisting of hydrogen, OR^3, NH_2, NHR^3, and halogen, Z is selected from the group consisting of =O, OH, NHR^3 , SH, and SR^3, wherein R^3 is C_{1-10} alkyl or aromatic cyclic group, $(C_7-C_8)_n$ includes at least one single bond or at least one double bond, n is an integer having a value of 0 to 10, and Y is selected from the group consisting of NH, NR^3-, O, and S. [with said symptom an effective amount of a compound as claimed in claim 1.]